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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,864	11/24/2000	David Scheinberg	D6126	4077
7590	05/18/2004		EXAMINER	
Dr. Benjamin Adler McGREGOR & ADLER, LLP. 8011 Candle Lane Houston, TX 77071			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,864

Applicant(s)

SCHEINBERG ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The finality of the previous Office action has been withdrawn, and the prosecution of this application is reopened to include art not previously cited.

It is noted that applicant has paid for a Notice of Appeal. Applicant can either request a refund or place the funds on credit for future appeals.

Applicant cancels claims 2, 4-6, 8-22.

Accordingly, claims 1, 3, 7, Bi-213, are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 1, 3, 7 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of a method for killing a solid tumor larger than 1 mm in diameter, comprising "systemically" administering a dose of high specific activity of Bi-213-antibody construct, has no clear support in the specification and the claims as originally filed.

A review of the specification discloses support for a method for killing a large tumor, preferably larger than 1 mm in diameter, comprising administering an alpha emitting construct to the tumor repeatedly (p.8, lines 4-6).

The subject matter claimed in claims 1, 3, 7 broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION

Claims 1, 3, 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for killing a solid tumor larger than 1 mm in diameter, comprising administering to a tumor a dose of high specific activity of Bi-213-antibody construct, does not reasonably provide enablement for a method for killing a solid tumor larger than 1 mm in diameter, comprising "systemically" administering a dose of high specific activity of Bi-213-antibody construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1, 3, 7 are drawn to a method for killing a solid tumor larger than 1 mm in diameter, comprising "systemically" administering a dose of high specific activity of Bi-213-antibody construct

The specification discloses a method for killing a large tumor, preferably larger than 1 mm in diameter, comprising administering the alpha emitting construct, Bi-213-antibody, to the tumor repeatedly (p.8, lines 4-6, and Examples 12-13, on pages 43-46). The specification further discloses that different from Ac-225, Bi-213 has short half life of 46 min, and targeting must be rapid (table 2 on page 22). It is noted that the medium

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serum half-life for an antibody is about 4.4 days (Maloney DG et al, 1994, Blood, 84 (8): 2457-66).

One cannot extrapolate the teaching in the specification to the scope of the claims. Although large solid peritoneal cancer could be effectively treated by Bi-212-antibody conjugate, when administered intraperitoneal, as taught by Simonson et al, of record, it is unpredictable that Bi-213-antibody, when administered systemically, could reach the large solid tumor in sufficient time to have sufficient radioactivity for killing large tumor, because of the short half-life of radiolabeled bismuth, such as Bi-212 and Bi-213, which could be mostly decayed before reaching the target cancer cells. Simonson et al, 1990, of record, teach that while the 1-h half-life of Bi-212 limits its therapeutic application, it may be especially appropriate when delivered i.p. for treatment of localized cancer (p.985s, first column, last paragraph).

In view of the absence of objective evidence, and in view of the teaching of the art, one cannot predict that Bi-213-antibody conjugate, when administered systemically, could reach the large solid tumor, which could be anywhere in the body, in sufficient time to have sufficient radioactivity for killing large tumor before the radioactivity is mostly decayed.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

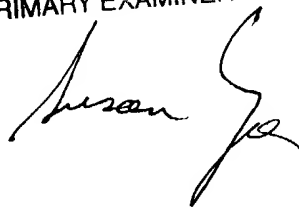
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

May 08, 2004

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan', followed by a large, stylized flourish or checkmark-like stroke.